Clinical Trial Conduct Training

Request for Expression of Interest

under
National Biopharma Mission (Industry- Academia Collaborative Mission for Accelerating Discovery Research to Early Development of Bio-pharmaceuticals)

Innovate in India (i3) Empowering Biotech Entrepreneurs & Accelerating Inclusive Innovation.

Funded by

Department of Biotechnology, Ministry of Science & Technology, Government of India

Co-funded through World Bank Loan Assistance

(Innovate in India for Inclusiveness Project)

through
Implementing Agency
Biotechnology Industry Research Assistance Council (BIRAC)

(A Government of India Enterprises)

Program Overview – National Biopharma Mission:

Industry-Academia Collaborative Mission for Accelerating Discovery Research To Early Development For Biopharmaceuticals - "Innovate in India (i3) Empowering biotech entrepreneurs & accelerating inclusive innovation", also referred to as National Biopharma Mission (NBM).

Funding agency:

Department of Biotechnology (DBT) (Program co-funded by World Bank loan).

Implementing agency:

Biotechnology Industry Research Assistance Council (BIRAC).

Background:

Towards strengthening the emerging biotechnology enterprise in India, Department of Biotechnology (DBT) Ministry of Science & Technology has initiated the Mission Program entitled "Industry-Academia Collaborative Mission for Accelerating Discovery Research to Early Development for Biopharmaceuticals - Innovate in India (i3) Empowering biotech entrepreneurs & accelerating inclusive innovation" ("Program"). Biotechnology Industry Research Assistance Council (BIRAC) setup by DBT is the Implementing Agency of i3 Program (Program co-funded by World Bank loan).

The vision of the program is to enable and nurture an ecosystem for preparing India's technological and product development capabilities in biopharmaceuticals including vaccines, biologics, medical devices, and diagnostics to a level that will be globally competitive over the next decade.

One of the key programs of the Mission is "Establishing Clinical Trial Networks and strengthening clinical trial capacity." Considering the limited capacity of Indian hospitals in handling regulatory compliant multiple clinical trials it is anticipated that delay in conduct of clinical trials can impact the development timelines of products. Based on the pipeline of products in India, NBM supported 46 sites for creation of hospital networks and epidemiology study sites and biologics, drugs and vaccine development. The site staff were also trained in general principles of Good Clinical Practices and Bioethics.

The pandemic made us realize the importance of clinical trial and at times, the urgency to recruit the eligible population. We also realized the gaps in this area and where our strengths can be leveraged. The clinical trial industry is a highly regulated environment with a primary focus on compliance to protocol and clinical standards, with the goal of delivering the highest quality data and protecting patient safety. It is essential that the staff are adequately trained, and understand the study protocol compliance.

Under the NBM skill development program, we intend to bring a **comprehensive hands-on training program for site staff to increase compliance and enhance quality with specifics of conducting a clinical trial.**

Request for Expression of Interest:
This Request for Expression of Interest (EoI) is to seek applications from suitable organizations that have appropriate capability and certification to conduct trainings for the following areas:

- Clinical Trial Conduct (Hands on Training) as mentioned below

Application Timelines: Key Dates

EOI Publication	11th December, 2024
Closing of Application	31st December, 2024 (5:00 PM IST)

Application Guidelines and Process:
The application can be submitted online as per the required format. The REOI will be open for 03 weeks from the date of publication.

Overview:
Clinical trials are essential for advancing medical research, developing new therapies, and ensuring patient safety. In India, the rapid growth of the pharmaceutical and biotechnology sectors has underscored the importance of conducting clinical trials in a compliant and efficient manner. However, the complexities involved in these trials require a well-trained workforce equipped with the necessary skills and knowledge.

Importance and Need of Clinical Trial Conduct Training:

Regulatory Compliance: India's regulatory landscape is evolving, with guidelines from the Central Drugs Standard Control Organization (CDSCO) and international bodies such as the ICH-GCP (International Council for Harmonization - Good Clinical Practice). Proper training ensures that researchers and trial staff understand and adhere to these regulations, minimizing risks of non-compliance.

Quality Assurance: High-quality data is critical for the approval of new drugs and therapies. Training in clinical trial conduct fosters best practices in study design, patient recruitment, data collection, and management, ultimately enhancing the quality and reliability of trial results.

Patient Safety: Ethical considerations are paramount in clinical trials. Training ensures that personnel are knowledgeable about informed consent, patient rights, and safety monitoring, thereby protecting participants and enhancing trust in clinical research.

Capacity Building: As India becomes a global hub for clinical research, there is a growing demand for skilled professionals. Training programs can help build a robust workforce capable of conducting trials efficiently and ethically, contributing to the country's position in the global research landscape.

Facilitation of Innovation: With proper training, researchers can more effectively design and implement innovative trials that could lead to breakthroughs in treatment. This fosters a culture of research and development, driving advancements in healthcare.

Hence, the need for clinical trial conduct training in India is critical to ensuring compliance, quality,

and safety in clinical research. By investing in the training of professionals in this field, India can enhance its contributions to global medical research and improve healthcare outcomes for its population.

Objectives of Clinical Trial Conduct Training:

1. **Introduction to Clinical development**: BA/BE; Innovative Molecules (NCE/NBE's; Generics). An overview of each class of drug development and requirements, various phases of clinical trials, Concepts of Statistical models, BA/BE designs, special studies (food effect, geriatric studies etc) applicable local and global laws.
2. **Enhance Understanding of Regulatory Requirements:**
   Equip participants with a thorough understanding of local and international regulatory frameworks, including guidelines from the Central Drugs Standard Control Organization (CDSCO) and ICH-GCP, to ensure compliance throughout the trial process.
3. **Promote Best Practices in Clinical Research:**
   Educate participants on industry best practices for study design, protocol development, and data management to improve the quality and integrity of clinical trials.
4. **Ensure Patient Safety and Ethical Conduct:** Under this the topics, such as patient informed consent (including audiovisual consenting) and related aspects like document control and consent forms, is generally guided by regulations and guidelines set by various authorities. This is to train participants on ethical considerations, informed consent processes, and patient rights, emphasizing the importance of prioritizing participant welfare in all clinical trial activities.
5. **Develop Skills in Risk Management:**
   Provide tools and techniques for identifying, assessing, and managing risks associated with clinical trials, fostering a proactive approach to potential issues.
6. **Enhance Data Management and Analysis Skills:**
   Teach participants effective methods for data collection, monitoring, and analysis to ensure accurate and reliable trial outcomes.
7. **Strengthen Communication and Collaboration:**
   Foster skills in effective communication and teamwork among clinical trial staff, researchers, and regulatory bodies, facilitating smoother collaboration throughout the trial lifecycle.
8. **Build Capacity for Emerging Therapeutics:**
   Prepare participants to conduct trials involving advanced therapies, including gene and cell therapies, addressing the specific challenges and regulatory considerations associated with these innovations.
9. **Support the Growth of India's Clinical Research Landscape:**
   Contribute to the development of a skilled workforce that can effectively support the burgeoning clinical research sector in India, enhancing the country's position in the global market.

By focusing on these objectives, clinical trial conduct training in India aims to build a robust foundation for conducting high-quality, ethical, and compliant clinical research.

Scope:

The training will be in-person (offline) only. Following training modules should be included, **along with at least 2 study-specific protocol trainings** designed to improve understanding of the protocol and study compliance

The training modules should be integrated with practical experience, preferably through role-playing and case studies

Training Modules:

Training/ Workshop	No. of participants
Awareness of Clinical Trials Rules & Regulations **Medical Device clinical trials and regulation in India** **Introduction to Randomized Controlled Trial: Design and Analysis (1 day)** - Techniques - Operations and Regulatory	
Taking patient informed Consent (AV consenting) As per the Drugs and Cosmetics Act & Rules (Schedule Y) and ICMR guidelines 2 days / (7-8 hours per day) - Elements & contents of consent form - Assent forms, Pharmacogenomic Consent Forms - Document Control - Common flaws in consent forms - Background of Audio-visual recording of consent - Conditions where AV consent is needed - Steps in AV recording process - Legal aspects to consider for informed consent - ICH-GCP Audio-Visual Consenting Process	
Managing and reporting AEs/SAEs (1-1.5 day, 7-8 hrs/day.) - Define Adverse Events, Serious Adverse Events and Adverse Drug Reactions - Documenting and Reporting Serious Adverse events - Expedited reporting of SAEs	
Good Documentation Practice (1-1.5 days 7-8 hrs/day) - Creating good quality documents - Filing and Identification of Documents - Non-Permanent Documentation	**Total 100 Candidates in 4-5 batches**

- Translations - Missing Documents - Corrections - Common types of documents - Essential documents	
Overview of Data Management (2 days, 7-8 hrs/day.) - Clinical Data Management Systems (CDMS) and EDC (Electronic Data Capture) - Data Entry Paper and Remote - Discrepancy management - Data Privacy and Storage	
Decentralized Clinical Trial Overview 1 day, 7-8 hr/day.) - Telemedicine and Remote Monitoring - Patient-Centric Design - Digital Data Collection - Centralized Data Management - Decentralized Drug Delivery - Regulatory Compliance and Ethical Considerations - Engagement and Support Services and Stakeholder Collaboration - Real-World Evidence Generation and Technology Infrastructure - Review of DCT (Decentralized Clinical Trial) guidelines	
A Session on hands on mock monitoring visit through a role play of various stakeholders like PI, Site coordinator, CRA, CRO, Lab Technician - **Study specific protocol trainings through role play of various stakeholders (8 hrs) (15-20 candidate per batch)**	

**The module content be taken as a reference and can be modified further to meet specific needs and objectives. There would be an assignment to assess comprehension of candidates on the all areas*

covered in the course.

These trainings are proposed to be organized by a training agency which fulfil the eligibility criteria.

Mode of trainings:

Only in-person (offline) training to be conducted

Terms of reference:
The selected training agency will take up all the responsibilities including the following:

1. Provide and execute complete plan on how to conduct the training.
2. Publication of advertisement in national newspapers/ publications in print media and related outreach to invite participants. Minimum 6 publications in newspapers to be done for various trainings.
3. Screening the applications for selecting the participants based on weighted scoring.
4. Conduct mock monitoring visits for selected participants
5. Availability of all the hardware / software arrangements to conduct the training course.
6. Assessment of the trainees after the course in the form of an examination
7. Certificates to be distributed to the participants.
8. Gather feedback on the course from trainees.
9. Maintain electronic traceability system (if any).
10. Completion of all trainings within 3-4 months from the official start date, on signing of the Grant-in-aid Letter of Agreement (GLA).

Important Note:

1. The trainings will be conducted by the agency on behalf of NBM and it should be mentioned at all possible places. All the activities related to the training must be done in consultation with NBM representative.
2. This training is proposed to be organized by a certified training agency which fulfil the eligibility criteria as per the Annexure – I, and Annexure - II.
3. BIRAC may also nominate trainees but enrolment in training will be subject to the fulfilment of selection criteria.

Applications process:
Agencies interested in organizing the trainings on behalf of NBM may submit their applications online only, through the submission link on BIRAC website (https://birac.nic.in). The online applications should reach to us by and before 5:00 PM IST on the last day of the application. Only successfully submitted online applications will be considered for further evaluation. No other modes of submission will be entertained

Acknowledgment of Submission:
Upon successful submission, applicants will receive an automatic acknowledgment via email. This acknowledgment will serve as confirmation that the application has been received.

Eligibility:
The applicant must furnish the details for general and technical eligibility criteria as per the templates provided as an annexure - I and annexure - II respectively.
The relevant supporting documents for eligibility check should also be uploaded and submitted along with the proposal.

Financial Details:
The details of the budget to plan, organize, and conduct the training should be furnished as per the training budget format provided as an annexure - III. The cost proposed in the application form should be inclusive of all costs (applicable taxes, reimbursable, sub-contracting, outsourcing, advisory etc.) required for the activities mentioned in the terms of reference and any other associated costs. No additional payments will be considered during evaluation process and/or after award of the grant.
After eligibility check, if called for technical and financial presentation, the applicant must also present each module-wise separate costing for all the components

Tentative Budget: Maximum up to INR. 55,00,000.00 for all 100 candidates (4-5 batches)

Evaluation and Decision-Making Criteria:
A selection committee will evaluate the proposals based on the application form, general and technical eligibility criteria (Annexure - I & II), budget details (Annexure – III), and declaration (Annexure IV) received from each applicant. Only qualified applicants as per the eligibility check by the experts, will be called through official communication for technical presentation(Travelling allowance will not be provided by NBM,BIRAC) for further review and screening. A final shortlisted applicant as per the expert's recommendations (from skill development committee of the BIRAC) will enter into the process of Grant-in-aid Letter of Agreement (GLA) execution. BIRAC's funding support as a grant-in aid under NBM to the qualifying applicant for the conductance of CTN training is subject to approval of the BIRAC's competent authority.

Post approval evaluation:

- Reporting of Progress - On Successful completion of each Milestone, the agency will be required to submit a detailed Milestone Completion Report (MCR) as per the prescribed format.
- The agency is required to take feedback from all the participants. The same would need to be submitted to BIRAC at the end of each batch of the training.
- The selected agency will also be evaluated based on the feedback received from the participants during a mid-term review. If negative feedback is received, the agency will be barred from participating in future bids
- Monitoring and review of the training implementation agency will be conducted by BIRAC's skill development committee, on completion of each milestone. The necessary recommendations on training implementation, changes required and financial disbursement

will be obtained from the committee for further actions.

Requisites for Funding:

Decision to fund will be as per sanction of the competent authority. Successful applicant shall enter into necessary funding agreements.

Financial support will be provided in 3 instalments -

- 50% of total payment after Acceptance of Undertaking under GLA and Signing of the GLA. Fulfilment of fund release requirements.
- 40% of the total payment after course completion for 60% of targeted participants.
- 10% of the total payment after course completion for 100% of targeted participants.
- After initial payment, next payment will be subject to the mid-term review and submission of CA audited utilization certificate (UC) and statement of expenditure (SoE) as per the standard template.
- The fund recipient shall be accountable for fund utilization as per the sanction.
- Re-appropriation of funds can be undertaken only after approval of BIRAC

Communication of Results:

- Accepted proposals will be informed via email within the review timeline.
- Rejected proposals will also be notified, and they may be provided with feedback upon request.

Special Circumstances:

- Any requests for deadline extensions, or special considerations must be submitted in writing to the organizing committee for review and decision.

Conflict of Interest

The decision of BIRAC shall be final in case of conflict of interest if arises

Confirmation of Participation:

- Selected applicants must confirm their participation within 05 days of receiving the acceptance notification from BIRAC. If confirmation is not received, the spot may be offered to waitlisted applicants.

Record Keeping:

- All submitted applications, along with the corresponding documents, will be archived in the designated folder or system governed by BIRAC.

BIRAC will maintain a record of accepted, waitlisted, and rejected applications

Expected outcome: Certified participants with the necessary training in conducting sponsored clinical trials

Contact Information:

Further information can be obtained at BIRAC website (www.birac.nic.in)

Contact Persons:
For queries about the application form:

Vandana Kaushal, Program Officer, NBM
Email: nbm-11@birac.nic.in

Dr. Madhvi Rao, Chief Manager, NBM
Email: nbm1@birac.nic.in

Clinical Trial Training – REOI

Annexure-1

Eligibility Evaluation Criteria

The following check points will be observed as a mandatory eligibility compliance from the applicant for the Clinical Trial Conductance Training

Sr. No.	Training AgencyEligibility Criterion	Supporting Documents attached (self-attested)	Page No of Supporting Documents	Eligibility Check (Yes/No)
General terms of reference				
1.	Indian companies/ entities – An Indian Company/ entity is defined as one which is registered under the Indian Companies Act, 2013/ under relevant Act and minimum 51% of the share/ stakes of the Company/ entity should be held by Indian Citizens holding Indian passport [Indian Citizens do not include Person of Indian Origin (PIO) and Overseas Citizenship of India (OCI) holders]. OR Non-profit organizations/ Government entities/ Institutes/ R&D Organizations – This will include Academic Research Institutes, Universities, Research Foundation, Medical Colleges and Institutes – both public and private who are valid legal entities such as Trust, Society or Corporations established under central or state statute			
2.	The Applicant must be registered in India with Taxation and other administrative authorities. The Applicant should also have a registered and established office in India.			
3.	The Applicant should not have pre-exited or terminated any contract with or by BIRAC in the last 05 years			

Annexure – II

Clinical Trial Training – REOI

Technical Eligibility Criteria

The following technical check points will be observed as a mandatory eligibility compliance from the applicant for Clinical Trial Conductance Training

Sr. No.	Training AgencyEligibility Criterion	Supporting Documents attached (self-attested)	Page No of Supporting Documents	Eligibility Check (Yes/No)
1.	The establishment should have experience of conductance of CTN training. Should have conducted a minimum of 5 trainings as lead trainer (essential for each trainer) as on date of closing of application.			
2.	There should be at least 2-3 certified trainers under each module of the RFP. (Conduct of minimum 5 trainings as lead trainer are essential for each trainer).			
3.	The training plan covers the following: i. Training design as per the RFP training modules ii. Training publications and outreach to invite applications from intenders iii. Screening and selection of trainees iv. Conductance of the training and necessary arrangements v. Assessment of the trainees after the course in the form of an assignment as explained in the RFP vi. Gather feedback on the course from trainees (in the beginning, in between, and at the end of the training), and share the feedback report to BIRAC			

Annexure – III

Training budget format

The details for training fund utilization under different budget head is given below. Applicant may follow the similar pattern of budget bifurcation for submission of their detailed budget requirement.

Expenditure Heads	Particulars	Proposed budget (Amount in INR.)
Training Design, Material and Conductance		
a. Training design and material	The training cost other than basic infrastructure, computational accessories, and stationary material)	
b. Outreach activity	For the publication of the training advertisement through social media handles and by outreach activities to multiple organizations, etc.	
c. Training conductance	Screening and recruitment of the candidate for the training. Training conductance material and consumable cost (computational accessories, stationary, certificate printing, training notes, feedback forms and reports, etc.)	
d. Honorarium	Honorarium cost to experts.	
Total (A)		
B. Logistic, Administrative and Miscellaneous Expenditure		
e. Logistic cost	Logistic cost includes lodging, boarding, and food of the trainees and experts). Travel cost (to and fro from accommodation place to training venue) for trainees and experts.	
f. Outsourcing	This includes any specific essential part of the training which need outsourcing	
g. Administrative	Administrative or contingency expenditure will be applicable only training related unexpected activities. Unjustified expenditure will not be considered while making the final release of the training grant amount.	
Total (B)		
Total A + B		

Annexure – IV

(To be printed on official letter head)

DECLARATION

1. I/We certify that the information in the above Expression of Interest in application form is true to the best of my knowledge.
2. I /We also understand that any misleading, or wrong information will disqualify this application straightaway.